Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

9/6/01

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

August 8, 2001

via Federal Express

MQSA Facility ID: 176313
Inspection ID: 1763130007

FDA Reference #: 2952033

Chester Lau, MD., Mammography Supervisor
Kern Medical Center
1830 Flower Street
Bakersfield, CA 93305

Dear Dr. Lau:

We are writing to you because on July 23, 2001, your facility was inspected by a representative of the State of California, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation presented at the time of the inspection, non-compliances were documented at your facility, as follows:

Repeat Level 2 Non-compliance:

1. Failure to produce documents verifying that the radiologic technologist [redacted] (10 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months

2. Failure to produce documents verifying that the radiologic technologist [redacted] (13 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months.

Note: This finding was also cited during the July 2000 inspection at which time your facility was also cited for failure of the interpreting physician to have the required

number of CMEs. Your facility has demonstrated a continuing problem with the documentation of continuing education requirements for its employees

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

The intent of this letter is to formally advise senior management of the Repeat Level 2 findings.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

Please submit your response to:

Russell A. Campbell, Compliance Officer
San Francisco District
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality

**This note is not applicable for letters which also address patient notification*

Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov/cdrh/mammography/index.html.*

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Russell A. Campbell at 510-337-6861.

Sincerely yours,

Dennis K. Linsley
District Director